United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

Dr. Satoshi Takaya, Director
Inspection and Safety Division
Food Sanitation Department
Ministry of Health, Labor and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku
Tokyo 100-8916, Japan

APR 2 2001

Dear Dr. Takaya:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Japan's meat inspection system from February 8 through 16, 2000. Enclosed is a copy of the final audit report. We received your December 28, 2000 comments on the draft final audit report and have included them as an attachment to the final audit report (Attachment G).

On December 5, 2000, FSIS sent a letter to Japan outlining two issues that were noted by the FSIS auditor and needed to be resolved by Japan. The first issue concerned Japan's Intra-laboratory Check Sampling Program. FSIS finds that Japan's response to this issue is not satisfactory. Japan must incorporate the following compounds into its monthly check sample program: Chloramphenicol, Invermectin, Diethylstibestrol, Benzimidazoles, Polychlorinated Biphenyls and Levamisole. Because Japan does not export swine to the United States, Carbadox for swine does not need to be included in the check sample program. Please advise FSIS by April 30, 2001 that the compounds listed above, except for Carbadox, have been included in Japan's monthly check sampling program.

The second issue concerned the holding of *Salmonella* samples under refrigerated temperatures for up to four days before analysis. As stated in your December 28, 2000 letter, Japan has agreed that in those cases where the samples cannot be analyzed on the same day as they are received, the samples will be stored at freezing temperatures. FSIS appreciates Japan's prompt action on this issue.

If you have any questions regarding the audit or need additional information, please contact me at 202-720-3781. My fax number is 202-690-4040.

Sincerely,

Sally Stratmoen

Sally Stratmoen, Chief
Equivalence Section
International Policy Staff
Office of Policy, Program Development
and Evaluation

Enclosure

United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha, NE 68102

AUDIT REPORT FOR JAPAN
FEBRUARY 8 THROUGH 16, 2000

INTRODUCTION

Background

This report reflects information that was obtained during a review of Japan's meat inspection system from February 8 through 16, 2000. The three establishments certified to export meat to the United States were audited.

The last FSIS audit of the Japanese meat inspection system was conducted in February and March 1998. The same three establishments were audited: all were acceptable. No system failures were reported.

Japan exports only beef to the United States. Restrictions are placed on Japanese pork due to the presence of hog cholera and swine vesicular disease in Japan (any pork would need special certification). Poultry products are ineligible because USDA does not recognize Japan's poultry inspection system as equivalent.

During calendar year 1999, Japanese establishments exported 32,027 pounds of beef to the U.S. There were no rejections at ports of entry.

PROTOCOL

This on-site review was conducted in four parts. One part involved visits with various Japanese national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of establishment records in the meat inspection headquarters facilities preceding the on-site visits. The third was conducted by on-site visits to establishments; and the fourth was a visit to three laboratories to determine whether system controls were operating in an effective manner: one performing analytical testing of field samples for the national residue testing program, one government laboratory testing field samples for the presence of microbiological contamination with *Salmonella*, and one private laboratory, associated with one of the establishments, where samples were tested for *Escherichia coli (E. coli)*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, and (5) enforcement controls. Japan's inspection system was assessed by evaluating these five

areas, with a special emphasis on Hazard Analysis – Critical Control Point (HACCP) Systems, Sanitation Standard Operating Procedures (SSOPs), and testing programs for *Salmonella* species and generic *E. coli)*.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in all of the three establishments; all were evaluated as acceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli,* are discussed later in this report.

Entrance Meeting

On January 20, an entrance meeting was held in the Tokyo offices of the Ministry of Health and Welfare (MHW), and was attended by Dr. Hideshi Michino, Deputy Director; Dr. Hisami Hiragi, internal reviewer; Mr. Tetsuo Hamamoto, Agricultural Specialist, American Embassy, Tokyo; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. Topics of discussion included the following:

1. Itinerary and lodging arrangements for the auditor were finalized.

2. The auditor shared with the MHW officials the updated data collection instruments for HACCP, *E. coli* testing, *Salmonella* testing, and SSOPs.

3. The auditor provided the MHW officials with the latest FSIS Regulatory & Enforcement Report (from FSIS's Internet home page), and inquired whether the Japanese system makes similar information available to the public. Dr. Michino replied that there was an annual report of inspection and enforcement activities which was available to the public as a published journal, and that there were plans to make it available on the internet in the near future. He also stated that data on food-poisoning instances was available on the Internet, and that the enforcement information may well take the same format.

4. Information was provided to update FSIS's country profile of Japan.

5. A questionnaire had been sent to all countries that are certified to export meat/poultry products to the United States early in 1999, requesting information on the residue testing programs. FSIS had not, as of the time of this meeting, received Japan's response. The auditor inquired when FSIS might expect this response, and the officials said they would provide an answer by the end of the country audit. It developed that the questionnaire had been sent to the wrong department, and the Agricultural Specialist was able to locate it and provide it to MHW within a few days.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. review of Japan's inspection system in February-March 1998.

Prior to the on-site audits of establishments, certain central documents were examined in the offices of the meat/poultry inspection headquarters, including records of the periodic internal supervisory reviews, the results of the 1999 national residue testing program and the 2000 residue testing plan. The latter two sets of data had not yet been provided to FSIS. Both were provided to the auditor immediately, and MHW officials stated that the same information was being forwarded to FSIS through normal channels.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the reviews of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The auditor observed and evaluated the process.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Japan as eligible to export meat products to the United States were full-time MHW employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

All three establishments certified to export meat products to the United States at the time this audit was conducted (Establishment numbers G-1, K-1, and M-1) were visited for on-site audits. In all these establishments, adequate MHW inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories,
2. Intra-laboratory quality assurance procedures, including sample handling, and
3. Methodology.

The Japan Food Residues Laboratories in Tama, a suburb of Tokyo, was audited on February 15, 2000. Effective controls were in place for sample handling, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recovery, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done.

The check sample program did not meet the requirements usually expected by FSIS. Intra-laboratory check samples were performed monthly only for chlorinated hydrocarbons, organophosphates, trace elements, and sulfonamides. For those classes of compounds for which intra-laboratory samples were not performed monthly, however, intra-laboratory check samples containing analytes unknown to the analysts *were* provided and run, and the analysts' performances evaluated, prior to the official analysis of routine field samples. During the previous audit of Japan, it had been noted that intra-laboratory check samples were run only every two months for chloramphenicol, thiamphenicol, ivermectin, carbamates, pyrethrins, mercury, arsenic, and antibiotics.

Japan's microbiological testing for *Salmonella* was being performed in government laboratories. One of these, the Chuo Meat Inspection Laboratory, Prefecture of Gunma, was visited. A data-collection instrument prepared by the Microbiology Division was employed to gather information about the methods and controls.

On the same day as the audit of Establishment G-1, the auditor visited the private laboratory, owned and operated by the establishment, in which swab samples were analyzed for the required testing for *E. coli*. The applicable portions of the data collection instrument used for the *Salmonella* testing laboratory were employed.

Establishment Operations

The three establishments were conducting beef slaughter and cutting operations. Each establishment received its livestock only from established contracted suppliers.

SANITATION CONTROLS

Based on the on-site audits of establishments, Japan's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; hand washing facilities; sanitizers; separation of operations; pest control and monitoring; temperature control; lighting; work space; ventilation; maintenance and cleaning of over-product ceilings and equipment; dry storage areas; personal dress, habits, and hygiene; equipment sanitizing; and product handling and storage.

Sanitation Standard Operating Procedures

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The Sanitation Standard Operating Procedures (SSOPs) were audited and found to meet the basic FSIS regulatory requirements.

Cross-Contamination

Hair was found on shanks and hocks of several carcasses in coolers and in the boning room in Est. G-1. The MHW reviewer ordered all to be reinspected and trimmed as necessary.

Maintenance in Product Handling Areas

1. Accumulations of rust were present on overhead structures in the offal room in Est. G-1 and buildups of rust and some flaking paint and condensation were observed on structures immediately over the operators and carcasses in the hindquarter skinning and bung-drop areas in Est. K-1. In both cases, establishment personnel agreed to increase maintenance and monitoring.

2. Numerous examples of unprofessional wiring were observed on the slaughter floor in Est. G-1: wires were twisted together and wrapped with old and deteriorating insulating tape without the use of junction boxes. MHW officials ordered correction.

ANIMAL DISEASE CONTROLS

Japan's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, humane handling and slaughter, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

Lighting at inspection surfaces of the beef sides anterior to the shoulders and shanks was inadequate (35 foot-candles) in Est. M-1. MHW ordered prompt installation of additional light to meet the 50 foot-candle requirement. During the previous audit of Japan, inadequate lighting had found at some areas of the official head inspection stations in two establishments (G-1 and M-1); this had been satisfactorily addressed.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

RESIDUE CONTROLS

Japan's National Residue Testing Plan for 1999 was being followed, and was on schedule. The Japanese inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The Japanese inspection system had controls in place to ensure adequate pre-boning trim and processed meat reinspection.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. The HACCP system in each of these establishments was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were audited and found to meet the basic FSIS regulatory requirements, with the following exceptions:

1. Both establishment and inspection personnel had been unaware of the requirement for a final review of all documentation pertaining to the monitoring of critical limits for the product included in each shipment eligible for export to the U.S. before that shipment leaves the establishment. (A review of the documentation of the monitoring of the critical limits showed that all had been measured as required and met.) The auditor explained the requirements for this pre-shipment review in detail; MHW ordered immediate implementation.

2. There was no equivalent of Noncompliance Records generated in the event of establishment personnel failing to comply with HACCP or SSOP responsibilities. The auditor explained in detail; MHW promised to implement such a system promptly.

Testing for Generic *E. coli*

The three establishments were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program and were found to meet the basic FSIS regulatory requirements. The data collection instrument used accompanies this report (Attachment C).

Control of *Listeria monocytogenes*

In response to the auditor's inquiry regarding the Japanese establishment officials' evaluation of their HACCP programs to address the risk of *Listeria monocytogenes,* the meat inspection officials provided this information:

> In Japan, information on food-borne illnesses, including those caused by *Listeria monocytogenes,* is gathered on a national basis. Physicians are required to report cases of such illness to the health center of the local government, and the local governments conduct epidemiological investigations and laboratory tests to determine the cause of infection. The health centers report the results to MHW through the head office of the local government.
>
> Non-typhoidal Salmonellosis is the most commonly reported food-borne illness in Japan. Most are caused by *Salmonella enteritidis,* and are associated with egg products. *Vibrio parahaemolyticus* is a well-known pathogen in Japan, associated with the high level of consumption of raw fish and shellfish. But *Listeria monocytogenes* infection has never been reported as [the source of] a food-borne illness.

ENFORCEMENT CONTROLS

Inspection System Controls

The MHW inspection system controls (ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, processed meat reinspection, shipment security, monitoring and verification of establishment programs and controls, inspection supervision, and documentation) were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

The three establishments were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program and were found to meet the basic FSIS regulatory requirements. The data collection instrument used accompanies this report (Attachment D).

Although *Salmonella* samples were usually analyzed on the same day they were received in the laboratory, it was reported that, on occasion, up to four days may elapse: in this case these samples were stored at 4.3ºC (40ºF) pending analysis.

Species Verification Testing

At the time of this audit, Japan was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

The internal audits in Japan were being conducted by two internal auditors, Drs. Hisami Hiragi and Makato Ozone, both of whom were veterinarians in the Veterinary Sanitation Division, under the direct supervision of the Chief of the meat inspection system, Dr. Kunio Morita.

No specific method was used for selecting the review dates of the establishments, but the dates varied from month to month. The internal audit program was applied only to export establishments. The internal audits were conducted once per month, and were announced to the inspection personnel, about two weeks in advance; the establishment officials were not informed in advance at all.

One copy of each internal audit report was kept in the headquarters of the Veterinary Sanitation Division of the Ministry of Health and Welfare in Tokyo; copies were also kept in the establishments. They were being maintained on file for a minimum of ten years.

If an establishment were to be found to fail to comply with U.S. requirements during an internal audit, it would be immediately delisted for U.S. export, and any products produced as of the start of business on the day of the audit would be ineligible for access to the U.S. market. No Japanese establishment has ever been found to be unacceptable, either by U.S. reviewers or by internal auditors.

After directly observing both of the internal auditors in Japan, the auditor was satisfied with the controls of this country's internal audit system with regard to the maintenance and enforcement of the requirements of the United States.

Enforcement Activities

Japan's compliance programs are governed by food sanitation laws that provide for regulation of meat production activities and for prosecution of fraud. There had been several violative residue investigations since the previous U.S. audit: MHW prepared a brief summary and provided it to the auditor at the exit meeting. This was filed in the Office of Policy, Program Development, and Evaluation (OPPDE).

Japan also had legal provisions in place to prevent anyone convicted of food industry violations from holding positions of authority (as owners or board members) in export meat establishments for a period of two years following the conclusion of the legal proceedings.

Exit Meetings

An exit meeting was conducted in Tokyo on February 16. The participants were Dr. Kunio Morita, Director, Veterinary Sanitation Division, MHW; Dr. Hideshi Michino, Deputy Director; and Dr. Hisami Hiragi, internal reviewer; Agricultural Specialist Mr. Tetsuo Hamamoto; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. The following topics were discussed:

1. The Agricultural Specialist had located the residue questionnaire, which had been sent to the wrong branch of the Japanese agency. He had already provided a copy to the proper meat inspection officials and had informed Washington that he had done so. The Japanese officials assured the auditor that they would formulate and submit a response to FSIS within a projected time frame of one week.

2. A copy of the most recent summary of incidences of foodborne illness in Japan (covering 1995-1998) was provided.

3. A summary of the results of several investigations into violative residues since the previous FSIS audit was provided, and has been filed in the offices of OPPDE.

4. The deficiencies identified were discussed in detail. The MHW officials reinforced the assurances made by field personnel during and at the conclusions of the on-site audits of the establishments, and stated that they would ensure prompt compliance regarding:

   · Improved maintenance and monitoring of over-product structures,
   · Correction of the unprofessional electrical connections,
   · Immediate implementation and monitoring, in all establishments, of pre-shipment document reviews,
   · Greater care to avoid contamination with hair on skinned carcasses,
   · Development by MHW of an instrument equivalent to the Noncompliance Record,

   · Installation of adequate lighting in Est. M-1, and
   · Upgrading of the reinspection criteria sheets to reflect the zero-tolerance policy for visible contamination with ingesta.

CONCLUSION

The inspection system of Japan was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Three establishments were audited: all were acceptable. The deficiencies encountered during the on-site establishment reviews were adequately addressed to the auditor's satisfaction.

Dr. Gary D. Bolstad
International Audit Staff Officer

(signed) Dr. Gary D. Bolstad

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for generic *E. coli* testing
D. Data collection instrument for *Salmonella* species testing
E. Laboratory audit form
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report (when available)

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used included the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
G-1	√	√	√	√	√	√	√	√
K-1	√	√	√	√	√	√	√	√
M-1	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. *The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.*
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or does not include records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. act's are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
G-1	√	√	√	√	√	√	√	√	√	√	√	√
K-1	√	√	√	√	√	√	√	√	√	√	√	√
M-1	√	√	√	√	√	√	√	√	√	√	√	√

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6, Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
G-1	√	√	√	√	√	√	√	√	√	√
K-1	√	√	√	√	√	√	√	√	√	√
M-1	√	√	√	√	√	√	√	√	√	√

Attachment D

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
G-1	√	√	N/A	√	√	√
K-1	√	√	N/A	√	√	√
M-1	√	√	N/A	√	√	√

Attachment E

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 2/15/2000

NAME OF FOREIGN LABORATORY: Japan Food Residue Laboratories / Tama Laboratory

FOREIGN GOV'T AGENCY: Ministry of Health and Welfare

CITY & COUNTRY: Tama / Tokyo, Japan

ADDRESS OF LABORATORY:

NAME OF REVIEWER: Dr. Gary D. Bolstad

NAME OF FOREIGN OFFICIAL: Dr. Tatsuko Yamakawa; Dr. Hisami Hiragi

	Residue Code/Name ▶			80	100	203	300	400	600	800	923				
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A	A	A	A	A	A	A	A				
	Sampling Frequency	02		C	C	C	C	C	C	C	C				
	Timely Analyses	03		A	A	A	A	A	A	A	A				
	Compositing Procedure	04		O	O	O	O	O	O	O	O				
	Interpret Comp Data	05		O	O	O	O	O	O	O	O				
	Data Reporting	06		A	A	A	A	A	A	A	A				
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	GC	A	A	A	A	GC	HP-LC	HP-LC				
	Correct Tissue(s)	08		Fat	A	A	A	L,K	A	A	A				
	Equipment Operation	09		A	A	A	A	A	A	A	A				
	Instrument Printouts	10		A	A	A	A	A	A	A	A				
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	0.1	A	A	A	A	0.05	A	0.05				
	Recovery Frequency	12		A	A	A	A	A	A	A	A				
	Percent Recovery	13		>70	A	A	A	A	>70	A	>70				
	Check Sample Frequency	14		C	A	C	A	A	C	A	C				
	All analyst w/Check Samples	15		A	A	A	A	A	A	A	A				
	Corrective Actions	16		A	A	A	A	A	A	A	A				
	International Check Samples	17		O	O	O	O	O	O	O	O				
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	C	O	C	O	A	C	O	C				
OTHER REVIEW		19	EVAL. CODE												
		20													

SIGNATURE OF REVIEWER: GD Bolstad

DATE: 2/15/2000

Designed on FormFlow Software

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
2/14/2000	G-1: Gunmaken Syokuniku-oroshiuri Shijyo Inc.	Takasaki
		COUNTRY: Japan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Gary D. Bolstad	Dr. Hisami Hiragi, Dr. Takashi Nakajima	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 N	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 A	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 M	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 M	SSOPs	82 A
Personal hygiene practices	26 A	Ingredients identification	53 O	HACCP	83 M
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
	2/14/2000	G-1: Gunmaken Syokuniku-oroshiuri Shijyo Inc.	Takasaki / Japan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Gary D. Bolstad	Dr. Hisami Hiragi, Dr. Takashi Nakajima	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

18 Accumulations of rust were present on overhead structures in the offal room. Establishment personnel agreed to increase maintenance and monitoring. Numerous examples of unprofessional wiring were observed on the slaughter floor: wires were twisted together and wrapped with old and deteriorating insulating tape without the use of junction boxes. MHW officials ordered correction.

51 Hair was found on shanks and hocks of several carcasses in coolers and in the boning room. The MHW reviewer ordered all to be reinspected and trimmed as necessary.

52 The Defect criteria sheet had not been updated to reflect the zero-tolerance policy for ingesta. Documents for several months were examined; no instances were found in which ingesta had been categorized as less than critical. MHW officials ordered immediate revision of the defect criteria sheets.

83 There had been no formal documented pre-shipment document reviews. The requirement for this had not been understood. This was to be corrected and implemented immediately. No equivalent of the Noncompliance Record was in place. This was to be rectified promptly.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
2/10/00	K-1: Minami-kyusyu Chikusan Kogyo Inc.	Sueyoshi
		COUNTRY: Japan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Gary D. Bolstad	Dr. Makato Ozone, Dr. Hisami Hiragi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 M	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 N	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 A	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 M	SSOPs	82 A
Personal hygiene practices	26 A	Ingredients identification	53 O	HACCO	83 M
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
	2/10/00	K-1: Minami-kyusyu Chikusan Kogyo Inc.	Sueyoshi / Japan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Gary D. Bolstad	Dr. Makato Ozone, Dr. Hisami Hiragi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

18/33 Heavy buildups of rust and some condensation and flaking paint were observed on structures immediately over the operators and carcasses at the hindquarter skinning and bung drop area. MHW ordered prompt correction and increased monitoring.

52 The boneless meat inspection criteria sheet had not been updated to reflect the zero-tolerance policy for ingesta. The auditor examined daily documentation for the past three months and found no instances in which ingesta had been evaluated as less than critical. MJHW officials immediately updated the defect criteria sheets.

83a The establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of documentation. The auditor explained in detail; MHW ordered immediate implementation.

83b There was no equivalent of Noncompliance Records generated as a result of establishment personnel failing to comply with HACCP or SSOP responsibilities. The auditor explained in detail; MHW promised to implement such a system promptly.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
2/9/2000	M-1:Miyazaki Kumiaisyouniku	Takasaki
		COUNTRY: Japan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Gary D. Bolstad	Dr. Makoto Ozone, Dr. Hisami Hiragi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 A
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 A
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 A
Lighting	11 M	Antemortem inspec. procedures	38 A	Interim container handling	67 A
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 A
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 A
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Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	2/9/2000	M-1:Miyazaki Kumiaisyouniku	Takasaki
			COUNTRY Japan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Gary D. Bolstad	Dr. Makoto Ozone, Dr. Hisami Hiragi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

11 Lighting at inspection surfaces of the beef sides anterior to the shoulders and shanks was inadequate (35 foot-candles). MHW ordered prompt installation of additional light.

83a The establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of documentation. The auditor explained in detail; MHW ordered immediate implementation.

83b There was no equivalent of Noncompliance Records generated in the event of establishment personnel failing to comply with HACCP or SSOP responsibilities. The auditor explained in detail; MHW promised to implement such a system promptly.

Veterinary Sanitation Division
Environmental Health Bureau
Ministry of Health and Welfare
Japan

Dr.Mark Manis
Director
International Policy Division
Office of Policy, Program Evaluation
and Evaluation

28th Dec. 2000

Dear Dr. Manis

This is in reply to your inquiry of Dec 5th about Japan's meat inspection system export to the United States.

The first issue you pointed out is about Japan's Intra-laboratory Check Sampling Program. The 2001 Intra-laboratory check sampling plan on monthly basis includes Polychlorinated Biphenils, Diethilstibestrol, Levamiosole, Chloramphenicol, Invermectine and Bensimidazole. As Japan exports only beef to the United States, carbadox is not included in the check sampling plan.

The second issue concerns Japan's *Salmonella* Testing program. *Salmonella* samples are usually analyzed on the same day they are received. In the case that the immediate testing in not possible, we directed to store samples at temperature below 0℃ in Dec. 2000.

If you have any questions, please don't hesitate to contact us.

Sincerely,

Satoshi Takaya
Director
Veterinary Sanitation Division
Ministry of Health and Welfare

Satoshi Takaya

Veterinary Sanitation Division Environmental Health Bureau Ministry of Health and Welfare, Japan
1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100 phone: 81-3-3595-2337 fax: 81-3-3503-7964